IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

CENTOCOR ORTHO BIOTECH, INC. and NEW YORK UNIVERSITY,	§	
Plaintiffs,	§	
v.	§	CASE NO. 2:07-CV-139-TJW
ABBOTT LABORATORIES, ABBOTT BIORESEARCH CENTER, INC., and ABBOTT BIOTECHNOLOGY LTD.,	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

In this case, plaintiffs Centocor Ortho Biotech, Inc. ("Centocor") and New York University ("NYU") (collectively "Plaintiffs") obtained a jury verdict of infringement against defendants Abbott Laboratories, Abbott Bioresearch Center, Inc., and Abbott Biotechnology Ltd. (collectively "Abbott") on June 29, 2009 with respect to claims 2, 3, 14, and 15 of United States Patent No. 7,070,775 ("the '775 patent"). (*See* Dkt. No. 261, Jury Verdict). On May 13, 2009 the Court ordered that equitable issues be bifurcated from the trial of jury issues. (Dkt. No. 211.) Abbott filed a pre-trial brief asking the Court to rule that the '775 patent is unenforceable due to inequitable conduct and prosecution laches and that the asserted claims are indefinite under 35 U.S.C. § 112 ¶ 2. (*See* Dkt. No. 280.) The Court conducted a bench trial on August 4, 2009 to resolve these equitable issues. Subsequent to that hearing and at the request of the Court, each party submitted proposed findings of fact and conclusions of law for these equitable issues. (*See* Dkt. Nos. 312, 317.) The Court has carefully considered the facts and arguments presented and

the applicable law in this case. For the following reasons, the Court finds that Abbott has not proven by clear and convincing that the '775 patent is unenforceable or invalid, and therefore rules in favor of the Plaintiffs.

II. BACKGROUND OF THE RELEVANT TECHNOLOGY

Centocor and NYU are co-assignees of the '775 patent, entitled "Recombinant A2-Specific TNFα Specific Antibodies." The '775 patent is directed towards anti-Tumor Necrosis Factor ("TNF") antibodies, fragments, and regions thereof which are specific for human tumor necrosis factor-α ("TNFα") and are useful in diagnosing and treating a number of TNFα-mediated pathologies and conditions. TNFα (cachectin) is a cytokine involved in the regulation of immune cells and is released in the body in response to endotoxins or other stimuli, or antigens. In healthy humans, the presence of TNFα has a normal regulatory affect on the immune system. Excessive TNFα production, however, can lead to inflammation and other symptoms that are associated with auto-immune diseases, such as rheumatoid arthritis, Crohn's disease, and psoriasis. In essence, the overproduced TNFα acts similar to a toxin and stresses the body. Typically, such stress is caused by a harmful foreign antigen, and the human immune system produces immunoglobulin proteins, or antibodies, that are specific to and neutralize a particular foreign antigen.

Antibodies have a structure universal to all types; they are constructed of two identical heavy chains and two identical light chains of amino acids. Each of the heavy and light chains may be divided into two regions, the constant region and the variable region. The constant region provides a general structure to the antibody, while the variable region provides the specificity of an antibody to a particular antigen. The specificity of an antibody comes from the amino acid chain in its variable region that has specific complementarity to the epitope of an

antigen.[1] The portion of the variable region that binds to the antigen is called the complementarity determining region ("CDR").

When an invading antigen is a human protein like TNFα, the immune system does not recognize the TNFα as a foreign antigen; accordingly, the human body does not have an immune response. The '775 patent is directed towards a TNFα antibody that enables the human immune system to neutralize this overproduced protein. As indicated above, the target protein TNFα naturally occurs in the human body, and the immune system does not create any antibodies against it. Consequently, the creation of an antibody specific to TNFα typically requires artificial engineering. Inherent with the engineering of TNFα specific antibodies, however, is a problem of immune response or immunogenicity issues—the antibodies must be specific to TNFα, yet must also not invite an immune response themselves. Accordingly, scientists have attempted to engineer antibodies with varying combinations of human and nonhuman materials. As mice produce antibodies specific to human TNFα, mice are the typical species used in such genetic engineering. The '775 patent specifically discuss a special antibody, designated A2, which has especially potent TNFα inhibiting activity. '775 patent, col. 43, ll. 35-41.

The '775 patent issued on July 4, 2006. The '775 patent culminates from an extensive and active prosecution history, spanning numerous patent applications across a fifteen-year period. The '775 patent is based upon application No. 10/198,845 ("the '845 application"), filed on July 18, 2002. U.S. Patent No. 7,276,239 ("the '239 Patent")[2] is a divisional patent of the '845 application and was issued on October 2, 2007. The '845 application is a continuation of

[1] The patent defines epitope as "that portion of any molecule capable of being recognized by and bound by an antibody at one or more of the [antibody's] antigen binding regions. Epitopes usually consist of chemically active surface groupings of molecules such as amino acids or sugar side chains and have specific three dimensional structural characteristics as well as specific charge characteristics." '775 patent, col. 13, ll. 15-21.

[2] The Plaintiffs also originally asserted the '239 patent against Abbott, but before the jury trial, based on certain stipulations, Plaintiffs only asserted claims 2, 3, 14, and 15 of the '775 patent. (*See* Dkt. No. 241.)

application No. 09/756,398, filed on January 8, 2001, now U.S. Patent No. 6,835,823, which is a division of application No. 09/133,119 filed on August 12, 1998, now U.S. Patent No. 6,277,969, which is a division of application No. 08/570,674, filed on December 11, 1995, now abandoned, which is a continuation-in-part ("CIP") of application No. 08/324,799, filed on October 18, 1994, now U.S. Patent No. 5,698,195, which is a CIP of application No. 08/192,102, filed on February 4, 1994, now U.S. Patent No. 5,656,272, and a CIP of application No. 08/192,861, also filed on February 4, 1994, now U.S. Patent No. 5,919,452, and a CIP of application No. 08/192,093, also filed on February 4, 1994, now U.S. Patent No. 6,284,471, which is a CIP of application No. 08/013,413, filed on February 2, 1993, now abandoned, which is a CIP of application No. 07/943,852, filed on September 11, 1992, now abandoned, which is a CIP of application No. 07/853,606, filed on March 18, 1992, now abandoned, which is a CIP of application No. 07/670,827, filed on March 18, 1991, now abandoned. Thus, Centocor filed its original application in the '775 patent family on March 18, 1991. All of these related applications are generally referred to as applications in "the '775 patent family."

III. INEQUITABLE CONDUCT

A. LEGAL STANDARD

"A patent may be rendered unenforceable for inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution." *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1313 (Fed. Cir. 2006); *see also* 37 C.F.R. § 1.56(a) ("Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.").

The materiality of information withheld during prosecution may be judged by the "reasonable examiner" standard. *See id.* at 1316. That is, "[m]ateriality . . . embraces 'any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a patent.'" *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998) (citations omitted). Moreover, "[i]nformation concealed from the PTO may be material even though it would not invalidate the patent." *Li Second Family Ltd. Partnership v. Toshiba Corp.*, 231 F.3d 1373, 1380 (Fed. Cir. 2000). "However, a withheld otherwise material prior art reference is not material for the purposes of inequitable conduct if it is merely cumulative to that information considered by the examiner." *Digital Control Inc.*, 437 F.3d at 1319. "[T]he scope and content of prior art and what the prior art teaches are questions of fact." *Id.*

"[T]he facts in inequitable conduct cases rarely, if ever, include direct evidence of admitted deceitful conduct." *Akron Polymer*, 148 F.3d at 1384. "The intent element of the offense is thus in the main proven by inferences drawn from facts, with the collection of inferences permitting a confident judgment that deceit has occurred." *Id.* "However, inequitable conduct requires not intent to withhold, but rather intent to deceive. Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible." *Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1367 (Fed. Cir. 2003). In addition, "a finding that particular conduct amounts to 'gross negligence' does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc in relevant part).

"The party asserting inequitable conduct must prove a threshold level of materiality and intent by clear and convincing evidence." *Digital Control*, 437 F.3d at 1313. "Only after adequate showings are made as to both materiality and deceptive intent may the district court look to the equities by weighing the facts underlying those showings." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co., et al.*, 537 F.3d. 1357, 1367 (Fed. Cir. 2008). "The court must then determine whether the questioned conduct amounts to inequitable conduct by balancing the levels of materiality and intent, 'with a greater showing of one factor allowing a lesser showing of the other.'" *Digital Control*, 437 F.3d at 1313 (quoting *Union Pac. Res. Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 693 (Fed. Cir. 2001)).

B. DISCUSSION

Abbott argues that Centocor committed inequitable conduct by repeatedly and knowingly making false and misleading statements to the United States Patent and Trademark Office ("USPTO") during the prosecution of applications in the '775 patent family. Abbott generally argues that Centocor's inequitable conduct falls under three categories, all related to a specific prior art antibody called MAK-195.

First, during prosecution of numerous applications upon which the '775 patent is based, specifically U.S. Patent Application Nos. 08/192,093, 08/192,861, and 08/192,102 (collectively, "the 1994 applications"), several different patent examiners rejected claims as obvious over publications by Moller et al., which disclosed an anti-TNFα murine antibody called MAK-195. Abbott argues that to overcome these rejections, Centocor made materially false statements to the USPTO about MAK-195 and its relationship to Centocor's murine anti-TNFα antibody, known as A2. Abbott argues that on five separate occasions Centocor represented to the USPTO that the two antibodies were different. Specifically, Centocor argued to the USPTO that it was

"unlikely" that the MAK-195 antibody was "specific for the same TNFα neutralizing epitope(s)" as the claimed antibodies and that a skilled artisan "would not conclude that any of the prior art antibodies are identical to or contain the features of the antibodies" claimed.

Abbott argues that these statements were materially false and misleading as Centocor's inventors would have known. Abbott argues that Centorcor's statements to the USPTO directly contradict correspondence from inventor Dr. Jan Vilcek to other co-inventors stating that MAK-195 had the same species specificity as A2 and that MAK-195 resembled A2 based on its species specificity. Specifically, in a letter dated August 1, 1990 to his co-inventors, inventor Vilcek noted that MAK-195 had "very potent neutralizing activity against human TNF" but failed to neutralize TNF from other species, with the exception of the chimpanzee, and stated that he would be testing whether A2 neutralized chimpanzee TNF given that A2 failed to neutralize TNF from other primates. Further, on August 15, 1990, inventor Vilcek sent another letter to the same co-inventors in which he reported that A2 did bind to chimpanzee TNF. He then stated that "[b]ased on our demonstration that MAb A2 neutralized chimp TNF, but failed to neutralize TNF produced in adherent cells of cynomolgus, rhesus or baboons, it appears that MAb A2 resembles [MAK-195] described by [the Moller reference], a copy of which I sent you about two week[s] ago." Inventor Vilcek then asked in the letter if "it would be worthwhile to request a sample of [MAK-195] in order to compare it side by side with Mab A2." In a 1993-1994 Progress Report, inventor Vilcek and another co-inventor noted that the species specificity of cA2 was "quite startling" in that it bound to human TNF but not baboon TNF even though "baboon TNF is known to differ from human TNFα in a single amino acid." Abbott argues the fact that both MAK-195 and A2 bind to TNFα from human but not TNFα from baboon, even though human and baboon TNF only differ by a single amino acid, means that this single amino

acid must be located in the epitope for MAK-195 and A2. Further, because MAK-195 also binds to human TNFα but not to baboon TNFα, Abbott argues that the epitopes for MAK-195 and A2 must be identical or highly similar and, as a result, these two antibodies will compete with each other for binding. Thus, Abbott argues that MAK-195 would contain the claimed feature of the antibodies, which is contrary to Centocor's arguments to the USPTO.

Abbott argues that Centocor's false and misleading statements to the USPTO were material. The rejected claims included claims covering antibodies that inhibited the binding of A2 to TNFα. The examiners' rejections cited the similarities between MAK-195 and A2 in reaching the conclusion that the antibodies appeared to "have the same or similar epitope binding specificities and M195 is expected to have the properties recited in the instant claims." Thus, Abbott argues that Centocor's misleading responses about the similarity of these antibodies went specifically to an issue that the examiners considered important in determining patentability, and were, therefore, material.

Regarding intent, Abbott does not provide direct evidence of intent but rather argues that in this case intent may be inferred from the surrounding circumstances. Abbott argues that the inventors of the 1994 applications were heavily involved in the patent prosecution and that the misleading statements were repeated on five separate occasions in three different patent applications. Thus, Abbott argues that the inventors were aware that these misleading statements were being made and that the inventors were clearly aware that species specificity was a material issue because multiple patent examiners issued rejections over Moller based on the species specificity of MAK-195. When asked about these misleading statements in the file history, all of the inventors claimed not to have any specific memory of reviewing them at the time. Further, Centocor's designated corporate representative on the issue of patent prosecution, who was also

personally involved in the prosecution of the 1994 patent applications and whom Abbott argues that it was reasonable to rely upon for information on the prosecution of the '775 patent, had no knowledge for the basis of the statements to the USPTO, did not know if anyone had reviewed the statements for accuracy, and could not even state whether the statements were accurate. Abbott argues that the corporate representative was obligated to have spoken with Ms. Elmore, the prosecuting attorney that Centocor now relies upon with respect to the contested statements made to the Examiner, to educate herself on the topic, and argues the fact that Centocor only recently relied upon Ms. Elmore's supposedly critical role with respect to the statements at issue until the day it filed its brief on equitable issues indicates that she had no helpful testimony for Centocor.

Second, Abbott argues that the inventors of the '775 patent and the Centocor patent attorneys committed inequitable conduct by failing to test MAK-195 to determine whether it did, in fact, compete with A2 as the examiners suggested and the inventors suspected. Abbott argues that, although as a general rule a party has no affirmative duty to search for relevant prior art, "one should not be able to cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art." *See FMC Corp. v. Hennessy Indus., Inc.*, 836 F .2d 521, 526 n.6 (Fed. Cir. 1987); *see also Brasseler, U.S.A., I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001). Abbott argues that the inventors of the '775 patent were aware of MAK-195 and its similar properties to A2 and were aware that the USPTO considered it an important issue. Abbott further argues that inventor Vilcek said as much and suggested obtaining MAK-195 so it could be compared side by side with A2, and despite repeated rejections by numerous patent examiners over the MAK-195 antibody, Centocor never tested the MAK-195 antibody. Abbott also argues that there is

evidence that Centocor had a sample of MAK-195. Thus, Abbott argues in this case, Centocor was not free to choose "not to investigate the facts necessary to determine the materiality of the reference" in an effort to avoid complying with their duty to disclose." *See Brasseler,* 267 F.3d at 1382. As result, Abbott argues that the '775 patent should be rendered unenforceable.

Third, Abbott argues that the inventors of the '775 patent and Centocor patent attorneys committed inequitable conduct by failing to cite the prior rejections over the Moller reference in the prosecution of the 1994 applications during the prosecution of the application leading to the '775 patent. Abbott argues that in 2002 when Centocor sought to broaden its claims to cover human antibodies, Centocor never cited the prior rejections in the 1994 applications to the new examiner. Specifically, in 2002, Centocor sought claims reciting antibodies that "competitively inhibit[] binding of A2 to TNFα," the same functional characterization repeatedly held insufficient by the prior examiner to overcome Moller in the 1994 applications. Abbott argues that the rejections from the 1994 applications in front of a different examiner were material because the previous claims were substantially similar to the claims in the application leading to the '775 patent. *See McKesson Info. Solutions, Inc., v. Bridge Med., Inc.,* 487 F.3d 897, 910-911 (Fed. Cir. 2007), *citing Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003). Abbott argues that Centocor was under a duty of disclosure to disclose material information from any source, including prior applications in front of a different examiner. Further, the new examiner for the application leading to the '775 patent specifically requested help from Centocor in understanding the complicated file history. Thus, Abbott argues that Centocor made materially false statements with an intent to deceive the PTO, and the '775 patent should be rendered unenforceable as a result.

In response, Centocor argues that it disclosed the Moller reference to the USPTO and that the arguments it made about the Moller reference were correct when made and are still correct today. First, in the Background section of the '775 patent specification, Centocor states that the inventors pointed out that "[o]ther investigators have described rodent or murine mAbs specific for recombinant human TNF which had neutralizing activity in vitro" and cited to the Moller reference. Second, in the section of the '775 patent specification describing the species specificity profile of A2, the inventors again pointed to the Moller reference: "The ability of A2 or cA2 to react with TNF from different animal species was also evaluated. As mentioned earlier, there are multiple epitopes on human TNF to which inhibiting and/or neutralizing mAbs will bind *(Moller, et al., infra)*…" Centocor also states that it disclosed the Moller reference in the "References Cited" portion of the '775 patent and in the Information Disclosure Statement. Thus, Centocor argues that it disclosed to the USPTO all the relevant facts known about the specific specificity of MAK-195 and the claimed A2 antibody.

Additionally, Centocor argues that all of the statements made to the USPTO to overcome the rejections were correct when made and are still correct today. Centocor summarizes those arguments as: (1) that it is unlikely that the Moller antibodies are specific for the same TNFα neutralizing epitope(s) as the [then] claimed antibodies, and (2) that a skilled artisan, based on the information in the Moller reference, would not conclude that any of the prior art antibodies are identical to or contain the features of the [then] claimed antibodies.

First, Centocor argues that it was correct at the time the argument was made to the examiner, and remains true today, that it is "unlikely" that MAK-195 is "specific for the same TNFα neutralizing epitope(s)" as the claimed antibodies. Centocor argues that, despite Abbott's attempts to blur the issues, during prosecution Centocor said nothing about whether the A2 and

MAK-195 antibodies might compete with one another for binding to TNFα and instead directed its argument to the likelihood that the two antibodies have the same epitope. Centocor argues that nothing in the Moller reference shows that the MAK-195 and A2 antibodies bind to the same epitope on TNF. Centocor argues the fact that MAK-195 and A2 share the same species specificity does not indicate that they share "the same" epitope for TNF. Further, Centocor argues that confidential Abbott testing from 2002 actually provides evidence that the epitopes of the two antibodies are different and that Abbott has also never even alleged, much less tried to prove, that MAK-195 and A2 are specific for the same epitope.

Second, Centocor argues that the prosecuting attorney's argument that "[a] skilled artisan, on the basis of the information disclosed in [Moller], would not conclude that [MAK-195 is] identical to or contains the features of the antibodies claimed by the Applicants" was also correct. Centocor argues that the Moller reference provides no basis for concluding that MAK-195 and A2 share the same epitope for TNF or are identical. Further, Centocor argues that Abbott presents the prosecuting attorney's arguments out of context and the features the prosecuting attorney was referring to were the chimeric structure of the antibodies and the superior clinical results for those antibodies, as found in the next few sentences of Centocor's responsive argument to the examiner. Thus, Centocor argues that it was true at the time and it remains true today, that one would not conclude from the Moller reference that the Moller antibodies would contain the features of the claimed antibodies, e.g., Moller does not describe chimeric antibodies and it does not describe superior clinical results.

Further, Centocor argues that the arguments made to the examiner, besides being correct, were not material. The arguments were not characterizing a prior art reference or the invention, but rather were arguing how one of skilled in the art would interpret the Moller reference.

Centocor argues that the reference was before the examiner, and thus the examiner was free to accept or reject the prosecuting attorney's arguments. Centocor also argues that there is nothing false or misleading about any of the arguments made to the USPTO, but, even if there were, there is no evidence that the prosecuting attorney or the inventors thought the statements made to the USPTO were in any way false or misleading, and, thus, no evidence from which intent to deceive can be inferred. Centocor argues that there is no evidence of deceptive intent on the part of the prosecuting attorney, Ms. Elmore, that made the arguments in the 1994 applications to the examiner, and that Abbott never even took the deposition of Ms. Elmore. Centocor further argues that there was no deceptive intent on the part of the inventors, that there was no evidence that the inventors ever saw or considered the specific arguments on which Abbott focuses, and that contrary to Abbott's arguments, that they were not "heavily involved in the patent prosecution."

Centocor argues that letters relied upon by Abbott between the inventors do nothing more than reflect the information, available from Centocor's patent specification and the Moller reference, that A2 and MAK-195 share certain species specificity properties. Centocor argues that the letters disclose nothing about whether A2 and MAK-195 shared the same or similar epitopes or whether they competed with one another for binding to TNF. Further, Centocor argues the fact that the two antibodies shared a degree of species specificity would not have indicated that the two antibodies had the "same epitope" or were in any way "identical." Centocor argues that even the inventors testified that information about the species specificity of MAK-195 and A2 is not enough evidence to support the scientific conclusion that the epitopes of the antibodies are the same or that they compete for binding to TNF.

Centocor also argues there is no evidence that it ever had a sample of MAK-195, and that even if it did have a sample, that it had no affirmative duty to test it. Centocor argues that it is aware of no case law, and that Abbott cites no case law, that places a requirement on an applicant to affirmatively obtain prior art samples and test them. Centocor also argues that Abbott failed to meet its burden on proving the elements of infectious unenforceability of how alleged misstatements in parent applications render the '775 patent unenforceable. Finally, Centocor argues it had no obligation to point the examiner to information that was in the '775 patent's own file history. Centocor argues that neither the *McKesson* nor the *Dayco* decisions relied upon by Abbott hold that a patent applicant is under a duty to bring to an examiner's attention rejections made earlier in the very file history of the application being examined. Rather, in both of those cases, there were co-pending applications in different patent families claiming similar subject matter. Centocor argues that the rejections Abbott highlights in this case were made in ancestor applications in the same family, were part of the file history for the '775 patent, and that the USPTO was completely informed of the existence of the parent and ancestor patent applications in the '775 patent family. Centocor argues that even if the rejections in the ancestor applications here could be deemed material to the '775 patent, intent to deceive cannot be inferred because Centocor expressly identified the ancestor applications in its application and standard examining practices required examiners to look at ancestor applications when carrying out their examination.

Based on the evidence of record, the arguments of counsel, and the applicable law, the Court finds that Abbott has failed to carry its burden of proving inequitable conduct by clear and convincing evidence. First, the Court finds that Abbott has failed to provide clear and convincing evidence of any material misrepresentation or omission during prosecution of the

applications in the '775 patent family. Evidence was presented showing that the prosecuting attorney's arguments to the USPTO were correct. Further, evidence was presented showing that the Moller antibody is unlikely to bind to the same epitope as cA2/A2. For example, Abbott's expert admitted on cross-examination that the epitopes for cA2/A2 and MAK-195 appear to be different. Evidence was also presented that indicates that the results of species specificity experiments for two antibodies do not provide enough information to know whether those antibodies bind to the same epitope. Evidence was also presented that indicates one would not conclude from the Moller reference that the Moller antibodies would contain the features of the claimed antibodies. The Court finds that the evidence presented is insufficient to meet Abbott's burden to show by clear and convincing evidence that the representations to the USPTO were false. As the Federal Circuit has said, "a prosecuting attorney is free to present argument in favor of patentability without fear of committing inequitable conduct." *Rothman v. Target Corp.*, 556 F.3d 1310, 1328-29 (Fed. Cir. 2009); s*ee also Young v. Lumenis, Inc.*, 492 F.3d 1336, 1348-49 (Fed. Cir. 2007) ("We therefore fail to see how the statements ... which consist of attorney argument and an interpretation of what the prior art discloses, constitute affirmative misrepresentations of material fact."). The Court finds that Centocor's statements to the examiners do not establish by clear and convincing evidence an effort to deceive the USPTO or make misrepresentations or omissions of material facts.

Second, the Court finds that Abbott has also failed to provide clear and convincing evidence that Centocor withheld any material information from the Examiner. Evidence was presented showing that the inventor's knowledge about MAK-195 was limited to the information that was disclosed in the Moller reference, information that was presented to the USPTO both in the form of the Moller reference itself, and by the prosecuting attorney's argument to the

examiner that the Moller reference described a "species specific murine monoclonal antibody, mAb 195, which neutralizes human TNF." Further, the Court notes that the disputed reference was before the examiner, was not a reference that was withheld from the USPTO, and thus the examiner was free to accept or reject the prosecuting attorney's arguments. *See Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008). Third, the Court finds that Abbott has failed to provide clear and convincing evidence that Centocor had a sample of MAK-195 and that Centocor had a duty to obtain and test a sample of MAK-195 in these circumstances. Fourth, the Court finds that Abbott has not proven by clear and convincing evidence that Centocor had a duty to cite to the Examiner prior rejections in the parent applications of the '775 patent, when the file history of the parent applications was already before the examiner. Even if Centocor had a duty to inform the examiner of the past history of the priority applications and such failure was material, the Court finds that Abbott has not proven by clear and convincing evidence that Centocor intended to deceive the USPTO by such omission.

Further, the Court finds that Abbott has failed to prove by clear and convincing evidence that the inventors, attorneys, or anyone else associated with the prosecution of the '775 patent or patent family intended to deceive the USPTO by their alleged misrepresentations or omissions of material facts. Abbott has not shown any direct evidence of intent, and instead asks the Court to infer intent. The Court finds that Abbott has not proven that inference of intent is appropriate under these circumstances. Abbott has not shown by clear and convincing evidence that the inventors or attorneys knew that any arguments made to the USPTO were false or misleading. As noted above, evidence has been presented showing that these arguments were not false or misleading. Further, there is evidence showing that the inventors and attorneys acted in good faith by ensuring that the USPTO knew about the Moller reference, such as by pointing out the

Moller reference in two different places in the specification, including in the section of the '775 patent specification describing the species specificity profiles, and by disclosing the Moller reference in an Information Disclosure Statement. Deceptive intent is not, in this case, the "single most reasonable inference." *Star Scientific*, 537 F.3d at 1366.

Thus, because the Court has found that Abbott has not satisfied its burden of proving that Centocor made material misrepresentation or omissions during prosecution of the '775 patent family or deceptive intent by clear and convincing evidence, inequitable conduct cannot be found in this instance. *See Star Scientific*, 537 F.3d at 1365-67.

IV. PROSECUTION LACHES

A. LEGAL STANDARD

Prosecution laches is an equitable doctrine that may be applied to bar enforcement of patent claims following "an unreasonable and unexplained delay in prosecution," even if the applicant technically complied with all pertinent statutes and rules. *Symbol Techs., Inc. v. Lemelson Med.*, 422 F.3d 1378, 1384-85 (Fed. Cir. 2005); *Aristocrat Tech. Australia Pty., Ltd. v. Int'l Game Tech.*, 543 F.3d 657, 664 n.4 (Fed. Cir. 2008) (citing *Symbol*, 422 F3.d at 1385, and noting that "prosecution irregularities" is distinct from "prosecution laches" and that "[p]rosecution laches stems not from any procedural lapse or irregularity during prosecution, but rather from an abuse of statutory provisions that results, as a matter of equity, in an unreasonable and unexplained delay in prosecution."). The Federal Circuit has cautioned that prosecution laches is a tool that has been used sparingly and "should be applied only in egregious cases of misuse of the statutory patent system." *Id.* at 1385. Courts have employed the doctrine of prosecution laches to a patent very infrequently.

"[T]here are no strict time limitations for determining whether continued refiling of patent applications is a legitimate utilization of statutory provisions or an abuse of those provisions." *Symbol*, 422 F.3d at 1385. The Federal Circuit has explained that there are legitimate grounds for refiling a patent application, such as to file a divisional application in response to a requirement for restriction, to present evidence of unexpected advantages of an invention when that evidence may not have existed at the time of an original rejection, or to add subject matter in order to attempt to support broader claims as the development of the invention progresses. *Id.* Even in the absence of these reasons, one may still refile an application as long as the refiling is not "unduly successive or repetitive." *Id.* By contrast, "refiling an application solely containing previously-allowed claims for the business purpose of delaying their issuance can be considered an abuse of the patent system." *Id.* The Federal Circuit has explained that "[t]aken singly, the delay in the prosecution on any one particular application will surely not appear to merit relief by the courts in equity. On the other hand, an examination of the totality of the circumstances, including the prosecution history of all of a series of related patents and overall delay in issuing claims, may trigger laches." *Id.* at 1385-1386.

B. DISCUSSION

Abbott argues that the fifteen-year prosecution history of the applications in the '775 patent family demonstrates a pattern of unreasonable and unexplained delays that materially prejudiced Abbott and the public. In particular, Abbott alleges that Centocor used the following delay tactics in the prosecution of the '775 patent family:

(1) initial filing delays, in which Centocor repeatedly filed incomplete applications in eleven of the twelve applications in the direct history of the '775 patent family, each with a receipt of notice to file missing parts;

(2) submission of improper drawings in two of the applications in the '775 patent family and the routine omission of genetic sequence data;

(3) requests for extensions of time for responses in nine of the twelve prior applications related to the '775 patent; and

(4) failure to speed abandonment by not requesting an express abandonment when it became clear that a patent would not issue from a given application.

In addition, Abbott alleges that Centocor failed to pursue claims expressly directed toward human antibodies before July of 2002, despite being based upon priority applications filed in 1994, and only did so after it learned that Abbott had developed and was about to market Humira, the product found to infringe the claims of the '775 patent. Thus, Abbott argues that Centocor's lengthening of prosecution in the '775 patent family served the purpose of allowing Centocor to continually attempt to "capture" the new and rapid developments in antibody technology that occurred during the 1990s. Abbott also argues that Centocor has not provided any legitimate excuses or explanation for this unreasonable delay. Specifically, Abbott argues that Centocor's corporate representative and Centocor's in-house patent counsel that supervised the filing of the '775 patent applications were unable to provide any information explaining the delays associated with the filing of the patent applications in the '775 patent family.

Abbott argues that it has been materially prejudiced by the delay. First, when Abbott purchased Knoll and the rights to Humira from BASF in 2000, not a single application or patent in the '775 patent family claimed human antibodies. Thus, Abbot argues that it and the public had no notice that human anti-TNFα antibody technology would be covered by patents arising from the '775 patent family. Further, because of this lack of foreseeability, BASF has refused to reimburse Abbott's expenses and litigation costs associated with the present suit. Second,

Abbott argues that Abbott invested substantial resources in the development of Humira before Centocor's claims to human antibodies were published in July 2003. Abbott argues that these investments were made without knowing that Centocor was planning on expanding the '775 patent family to cover human antibody technology. Further, had Abbott known of Centocor's human antibody claims in 2002, it could have sought a license during its negotiations with Centocor to cover Humira at the same time when it reached a cross-license agreement with Centocor in December 2002 regarding various antibody technologies. Finally, Abbott argues that Centocor's delay affected the judicial process and Abbott's ability to defend itself. Abbott argues that Centocor repeatedly attacked Abbott's anticipation defense based because of the age of a sample CDP-antibody tested. Abbott also argues that the delay prejudiced Abbott's inequitable conduct defenses because, given the passage of time, Centocor witnesses were unable to recall details relating to MAK-195 and the statements made during prosecution of the '775 patent family applications regarding MAK-195.

In response, Centocor argues that the prosecution of the '775 patent and applications within the '775 patent family was not unreasonable, was consistent with practices in prosecution of life science patents, and that Abbott was not prejudiced by any alleged delay. Further, Centocor argues that prosecution laches only applies in egregious situations as explained in *Symbol Techs.,* 422 F.3d at 1385. Centocor argues that Abbott presented no evidence regarding what practices are considered reasonable in the prosecution of life sciences patents. Centocor argues that the '775 patent family was prosecuted with reasonable diligence and that the prosecution was consistent with the general practice in the life sciences area. Centocor argues that, following common prosecution goals in the biotechnology field, claims were first drawn narrowly to Centocor's commercial cA2 antibody and methods of its use, and later sought

protection on other aspects of its invention. Common in the field of biotechnology, Centocor argues that it filed CIP applications to add information learned about the invention as its research continued, such as including additional information about human antibodies and how they are made, as well as the results of clinical trials reflecting the use of an antibody of the invention to treat various diseases. Further, Centocor argues that in the '775 patent family it filed each subsequent application in the family well in advance of a previous application either issuing or going abandoned.

Centocor also argues that in July 2002 when it filed claims directed to chimeric and human anti-TNFα antibodies that it had begun development of its own human anti-TNF antibody. Centocor argues that it was not until August 2005 that Centocor conducted competition testing with Humira and cA2 to determine whether the pending claims directed to human antibodies cover Humira, and that after finding that Humira and cA2 compete for binding as required by the pending claims, Centocor notified the patent office that the claims cover Humira. Centocor argues that it is not unusual or improper to draft claims to cover a competitor's product, as long as there is a basis in the pending application. Centocor further argues that there is no evidence that Abbott's development of a human anti-TNFα antibody prompted Centocor to file claims covering human anti-TNFα antibodies in July 2002.

Centocor argues that prosecution predating the filing of the 1994 applications, including the abandonment of five applications and two filings of incomplete drawings, is irrelevant to the determination of prosecution laches because the Court has previously ruled that Centocor cannot claim priority for the '775 patent on applications before 1994. Centocor also argues that Abbott has presented no evidence that the filing of incomplete applications resulted in the delay of prosecution. Centocor also argues that it is common to file an extension of time in the

pharmaceutical or biotechnology field, and that extensions of time do not necessarily delay the prosecution of an application. For example, Centocor argues that taking extra time to draft a more persuasive and complete response to an office action by the filing of an extension can result in getting an earlier notice of allowance and actually shorten prosecution. Further, Centocor argues that most of the extensions of time requested by Centocor could not delay prosecution of the '775 patent because they were taken after a subsequent CIP application was already filed.

Centocor also argues that Abbott was not prejudiced by any alleged delay. Centocor argues that Abbott has yet to fully pursue the issue of indemnification with BASF, and Abbott has not, but could, bring a lawsuit against BASF to require them to honor the indemnification provision. Centocor also argues that by August 12, 1997, when U.S. Patent No. 5,656,272 ("the '272 patent"), a patent arising from an application in the '775 patent family, issued and before Abbott entered into the agreement with BASF, anyone looking at the '272 patent would have known that the summary of the invention disclosed human anti-TNF antibodies, and thus the public was put on notice that the '775 patent family included disclosure directed to human anti-TNFα antibodies. Centocor also argues that Abbott presented no evidence to support its alleged prejudice of being prevented from acquiring a license covering Humira during negotiations with Centocor in 2002, and in any event, Abbott's argument is contradicted by Abbott's own statements during this litigation that it thought it had an express or implied license to the '775 patent. Centocor also argues that Abbott presented no evidence to support its alleged harm from any evidentiary prejudice and that Abbott itself bears the responsibility for failing to prove the authenticity of the prior art sample of CDP-571 antibody that was tested and relied upon by Abbot for its anticipation defense. Finally, Centocor argues that any alleged delay in prosecuting the '775 patent family actually worked to Abbott's benefit and Centocor's detriment because the

'775 patent will expire 20 years from the filing of the earliest application in the patent family and Centocor can only collect damages for Abbott's infringement of the '775 patent from the date it issued on July 4, 2006. Had the prosecution of the '775 patent ended earlier, Centocor argues that Abbott could have collected millions if not billions of additional dollars from the sale of Humira.

The Court has considered the totality of the circumstances in this case, including the prosecution history of all the applications leading to the '775 patent, and finds that Abbott has not met its burden of proving that there was any unreasonable delay by Centocor in the prosecution of the applications in the '775 patent family. Although the prosecution of the '775 patent family was lengthy, duration of prosecution provides no bright-line rule as to the reasonableness of the prosecution. *See Symbol*, 422 F.3d at 1385. Centocor provided reasonable explanations for its lengthy prosecution of the applications in the '775 patent family. Indeed, Centocor was successful in obtaining numerous patents from the applications leading to the '775 patent. Further, the Court finds that Abbott, in contrast to Centocor, presented no evidence regarding what practices are considered reasonable in the prosecution of life sciences patents. Centocor's explanation of initially presenting narrowly drawn claims covering its commercial products in the '775 patent family and then seeking broader protection on other aspects of its invention is reasonable. The delays that Abbott complains about in the prosecution history do not amount to an unreasonable delay based upon the totality of circumstances during the prosecution of the '775 patent family. The Court also finds that Abbott did not meet its burden to show that Centocor used delay tactics in presenting claims directed to human antibodies. It is not unusual or improper to draft claims to cover a competitor's product, as long as there is a basis in the pending application. *See Kingsdown*, 863 F.2d at 874 ("there is nothing improper,

illegal, or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market"); *PIN/NIP, Inc. v. Platte Chemical Co.*, 304 F.3d 1235, 1247 (Fed. Cir. 2002) ("While it is legitimate to amend claims or add claims to a patent application purposefully to encompass devices or processes of others, there must be support for such amendments or additions in the originally filed application.")

Abbott has not shown why Centocor's actions are to be considered an abuse of the patent system or are so egregious as to invoke the doctrine of prosecution laches. *Symbol*, 422 F.3d at 1385. The Court finds that this is not a case where there was "an unreasonable and unexplained delay in prosecution." *Id.* Further, the Court also finds that Abbott has not proven that it has been prejudiced by any actions of Centocor, and any arguments to the contrary by Abbott are merely speculative. Thus, the Court finds that the '775 patent should not be held unenforceable under the doctrine of prosecution laches.

V. INDEFINITENESS

A. LEGAL STANDARD

A claim is invalid for indefiniteness if it fails to particularly point out and distinctly claim the subject matter that the applicant regards as the invention. 35 U.S.C. § 112, ¶ 2. To prevail on an indefiniteness argument, the party seeking to invalidate a claim must prove "by clear and convincing evidence that a skilled artisan could not discern the boundaries of the claim based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." *Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008). The primary purpose of the definiteness requirement is to ensure public notice of the scope of the patentee's legal right to exclude, such that interested members of the public can determine whether or not they infringe. *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d

1342, 1347 (Fed. Cir. 2005); *Halliburton*, 514 F.3d at 1249; *Honeywell Int'l Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1338 (Fed. Cir. 2003). Courts apply the general principles of claim construction in their efforts to construe allegedly indefinite claim terms. *Datamize,* 417 F.3d at 1348; *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1346 (Fed. Cir. 2007). A claim is indefinite only when a person of ordinary skill in the art is unable to understand the bounds of the claim when read in light of the specification. *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993); *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1371 (Fed. Cir. 2008). A determination of claim indefiniteness is a conclusion of law. *Exxon Research & Eng'g Co. v. United States,* 265 F.3d 1371, 1375-76 (Fed. Cir. 2001); *Datamize,* 417 F.3d at 1347.

A claim is indefinite only if the claim is "insolubly ambiguous" or "not amenable to construction." *Exxon,* 265 F.3d at 1375; *Young*, 492 F.3d at 1346; *Halliburton*, 514 F.3d at 1249; *Honeywell*, 341 F.3d at 1338-39. A court may find a claim indefinite "only if reasonable efforts at claim construction prove futile." *Datamize*, 417 F.3d at 1347. A claim term is not indefinite solely because the term presents a difficult claim construction issue. *Id.*; *Exxon*, 265 F.3d at 1375; *Honeywell*, 341 F.3d at 1338. "If the meaning of the claim is discernable, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, ... the claim [is] sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon*, 265 F.3d at 1375; *Halliburton*, 514 F.3d at 1249.

B. DISCUSSION

The Court interpreted the claim language "competitively inhibits binding of A2 (ATCC Accession No. PTA-7045) to human TNF-α" to mean an antibody must "compete[] with A2 (ATCC Accession No. PTA-7045) for binding to human TNF-α" in order to infringe the claims. Abbott argues that as defined, the limitation does not permit a person of ordinary skill in the art

to "understand the bounds of the claim." Abbott raised this issue at claim construction and the Court ruled on it in its Markman Order, adopting Centocor's claim construction. However, Abbott asks that to the extent the Court has not ruled on the issue, Abbott restates its indefiniteness argument, and to the extent the Court has ruled on the issue, Abbott requests an order preserving the issue for appeal.

Abbott argues that nothing in the '775 patent provides the proper test parameters that one of ordinary skill in the art would use to understand the scope of the claim. Abbott argues that there is little disclosure of the appropriate test conditions to determine competition, and that the '775 patent specification is silent on what level of competition is required by the claims. Abbott argues that there is no scientific definition about when inhibition of binding of one antibody to another is of a degree that the antibodies can be said to compete with one another. Abbott further argues that depending on the antibody and assay conditions, different antibodies might inhibit binding of A2 a little, a medium amount, or completely. Thus, Abbott argues that different assays could yield different inhibition of binding results with the same antibodies.

Centocor argues that Abbott presented no evidence showing that the "competitive inhibition" claim element, as construed by the Court, is insolubly ambiguous. Centocor argues that Abbott's suggestion that the claims are invalid because the '775 patent is silent with respect to what level of competition is required by the claims is based on mere speculation. Centocor argues that Abbott's arguments are belied by the fact that Abbott's expert admitted that scientists experienced in the field are competent to determine the temperature, solvents, and relative amounts of antibodies to use in a competition assay, and that he had no problem with the competition test protocols or data generated by a Centocor scientist to show antibody competition. Centocor also argues that there is no evidence that Humira competes with A2 under

one set of test conditions, but not under another set of test conditions. Finally, Centocor argues that there was no disagreement between witnesses at trial with respect to whether two antibodies competed for binding to TNFα based on the quantitative level of competition required by the claims.

The Court first notes that it has already rejected Abbott's arguments that the "competitively inhibits" language is indefinite in its Markman Order in this case. The Court again finds that Abbott has not shown by clear and convincing evidence that those skilled in the art would not understand the bounds of the claims or that the claims are "insolubly ambiguous." Abbott has failed to prove that the results of competition testing will change depending on the assay conditions. Further, the Court finds that the evidence adduced during the jury trial shows that those skilled in the art would understand the bounds of the asserted claims. For example, Abbott's expert relied on antibody competition testing done by a different retained expert to support his conclusions about invalidity in this case. Abbott's expert also did not contest the protocols used by a Centocor scientist to show antibody competition or the quality of the results. Thus, the Court finds that Abbott has failed to show by clear and convincing evidence that the claim term "competitively inhibits" is "insolubly ambiguous," and thus the Court finds that the '775 patent is not invalid for indefiniteness. *Exxon,* 265 F.3d at 1375; *Young*, 492 F.3d at 1346.

VI. CONCLUSION

The Court finds that Abbott has not carried its burden of proving by clear and convincing evidence that the '775 patent is unenforceable or invalid. The Court finds that Abbott has not proven by clear and convincing evidence that Centocor committed inequitable conduct or prosecution laches during prosecution of the applications in the '775 patent family. The Court further finds that Abbott has not proven by clear and convincing evidence that the claim term

"competitively inhibits" of the '775 patent is invalid for indefiniteness. Thus, the Court finds that the '775 patent is not invalid or unenforceable and therefore rules in favor of Centocor.

IT IS SO ORDERED.

SIGNED this 4th day of November, 2009.

T. John Ward

T. JOHN WARD
UNITED STATES DISTRICT JUDGE